DETAILED ACTION

Claim Objections

Claims 35 and 37 objected to because of the following informalities: The typo "sodium hypochloride" should be "sodium hypochlorite". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-27 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 21-27 and 39-40, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Accordingly, dependent claims 22-27 and 39-40 are indefinite.

Regarding claims 24-26, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 27, the phrase "is possibly associated with" renders the claim indefinite because it is unclear what the association is.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-24, 26-27, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Steinmann *et al.* (US 5,456,723).

Regarding claims 21-22 and 39-40 : Cougoulic teaches a material for medical or veterinary use designed for the execution of endo-bone implants, bone prostheses [instant claim 40], and dental implants [instant claim 39] (1:5-12), wherein the material is in the form of a molded part made of a biocompatible thermoplastic polymer {binder} containing at least one compound for adding calcium or phosphorous (1:35-62; 2:56-60; 3:20-4:20), wherein the material comprises a thermoplastic polymer in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite [instant claim 22] (1:55-2:3; 2:61-3:14).

Cougoulic does not teach a material comprising a surface having micropores [instant claim 21]. However, Steinmann *et al.* teaches implants applied to human or animal bone having a porous surface (1:10-22), wherein the contact surface is provided with micro-roughness having a fine pitting superimposed thereon (about 2 μm) {micro-pores} [instant claim 21] (3:2-6; 3:21-24). Cougoulic and Steinmann *et al.* are combinable because they are concerned with a similar

technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined a contact surface with micro-roughness having a fine pitting superimposed thereon (about 2 μm) {micro-pores}, as taught by Steinmann *et al.* in the invention of Cougoulic, and would have been motivated to do so since Steinmann *et al.* suggests that such micro-pores provide an interface where bone will readily intergrow with the implant and will speedily form with a bond that is strong and durable and capable of resisting all of the mechanical forces it will be exposed to during its use (2:45-50; 3:20-24), and is an equivalent alternative means of providing a medical (bone and dental) implant.

Regarding claims 23-24: Cougoulic teaches the binder is a thermoplastic polymer [instant claim 23], specifically polyetheretherketone (PEEK) [instant claim 24] (2:23-43).

Regarding claim 26: Cougoulic teaches TiO_2 (2:44-50).

Regarding claim 27: Cougoulic teaches chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and metallic oxide (TiO_2) (2:61-3:14).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Steinmann *et al.* (US 5,456,723), as applied to claim 21 above, and in further view of Ellingsen *et al.* (US 2002/0111694).

Regarding claim 25: Cougoulic and Steinmann *et al.* renders the basic claimed composition obvious [as set forth above with respect to claim 21].

Cougoulic does not teach cellulose as a binder. However, Ellingsen *et al.* teaches medical prosthetic devices and implants (bone and dental) comprising cellulose as a biopolymer (¶ 2, 9, and 19). Cougoulic and Ellingsen *et al.* are combinable because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined cellulose, as taught by Ellingsen *et al.* in the invention of Cougoulic, and would have been motivated to do so since Ellingsen *et al.* suggests that cellulose provides tissue resilience, strength, rigidity, and integrity of the extra-cellular matrix (¶ 21), and is an equivalent alternative means of providing a medical (bone and dental) implant.

Claims 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of in view of Steinmann *et al.* (US 5,456,723), in further view of Mills *et al.* (US 6,482,584).

Regarding claims 28-38: Cougoulic teaches a method for preparing a material for medical or veterinary use (1:5-12), wherein the material is prepared by mixing a mixture comprising a thermoplastic polymer in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and subjected to molding operations (1:35-2:3; 2:61-3:14; 3:43-4:15).

Cougoulic does not teach a material comprising a surface having micropores [instant claim 28], nor a pickling process with HCl [instant claim 32]. However, Steinmann *et al.* teaches implants applied to human or animal bone having a porous surface (1:10-22), wherein the

contact surface is provided with micro-roughness having a fine pitting superimposed thereon (about 2 μm) {micro-pores} [instant claim 28] (3:2-6; 3:21-24), prepared by a pickling process in hydrochloric acid [instant claim 32] (3:8-15). Cougoulic and Steinmann *et al.* are combinable because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined a contact surface with micro-roughness having a fine pitting superimposed thereon (about 2 μm) {micro-pores}, as taught by Steinmann *et al.* in the invention of Cougoulic, and would have been motivated to do so since Steinmann *et al.* suggests that such micro-pores provide an interface where bone will readily intergrow with the implant and will speedily form with a bond that is strong and durable and capable of resisting all of the mechanical forces it will be exposed to during its use (2:45-50; 3:20-24), and is an equivalent alternative means of providing a medical (bone and dental) implant.

Cougoulic does not teach surface pickling or decontamination operations on the molded material, nor packaging aseptically of the decontaminated material [instant claim 28]. However, Mills *et al.* teaches a method of cleaning/sterilizing implants, as well sterile packaging of the implant (1:5-14; 3:65-4:11; 14:34-55), comprising subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions [instant claim 28] (4:14-41) in a chamber which permits sonication of the contents (4:52-54; 6:49-58) [instant claim 29-31 and 38]. The surface treatment includes solutions of: HCl [instant claim 32] (14:5-21, Table II (J)), acetone [instant claim 33] (14:5-21, Table II (J)); hydrogen peroxide [instant claim 34] (4:14-18), sodium hypochlorite [instant claim 35] (14:5-12), Betadine or isopropanol {decontaminating product} [instant claim 36] (4:14-18; 14:5-21), and sterile water [instant claim 37] (11:28-33, Tables I and

II). Cougoulic and Mills *et al.* are combinable because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents, and sterile packaging of the implant, as taught by Mills *et al.* in the invention of Cougoulic, and would have been motivated to do so since Mills *et al.* suggests that such processes provide penetrating sterilization of the implant, wherein the channels of the porous matrix are unclogged and cleansed (8:14-26), and is an equivalent alternative means of providing a medical (bone and dental) implant.

The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. See attached form PTO-892.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pepitone whose telephone number is 571-270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/MARK EASHOO/
Supervisory Patent Examiner, Art Unit 1796
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